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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/415,890	10/08/99	ANDERSSON	UTXC:528--1

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HM12/0315

EXAMINER

LEVY, N

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

415890

Applicant(s)

ANDERSON

Examiner

MELBY

Group Art Unit

1616

6

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 1/23/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 16-23, 26-80 is/are pending in the application.
- Of the above claim(s) 89-80 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 26-68 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1616

Receipt is acknowledged of Pre amendment (10/8/99) and election (1/23/01).

Applicant's election without traverse of Group II in Paper No. 5 is acknowledged.

Claims 16-23, 69-80 stand withdrawn from further consideration pursuant to 37

CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 36, 38, 48, 49, 53-55, 60-62, 65, 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Distinguishing between parental fluids and the other species, also able to constitute parental fluids, is impossible to do (Claim 34). Abbreviations need to be spelled out at first appearance in claims, and Trademarks are NOT permitted (Claims 36, 38) please further identify generically, Trademark ingredients in the claims. As in claim 34, the claim 49 species are NOT mutually exclusive, and similarly in claim 65, 66-parenteral is all inclusive.

Art Unit: 1616

Claim 68 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim 26 vehicle and claim 68 are contradictory absent specification lyophilizable vehicles

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 26-28, 30-34, 41-45, 47-52, 57-59, 63-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al 5,559,148.

Solvent vehicles are known comprising physiologically acceptable formulation vehicles and components for parenteral administration (Col. 3, bottom) inclusive of the instant polyethylene glycols, and other of (claim 22, Col. 4) at the instant concentrations, in combination or equivalent solvent vehicles (see Table 1, Example 2).

Claims 26-28, 30-34, 41-45, 47-52, 57-59, 63-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al 5,430,857.

As above, the instant vehicles, injectable compositions and concentration of ingredients meet the instant invention as claimed.

Art Unit: 1616

Claims 26, 27, 29, 32, 34, 35, 37-42, 47-49, 63-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Sugiyama et al 5,651,991.

See examples 1, 4; pharmaceutically acceptable dipolar aprotic solvents (see Col 7, lines 63-line 4, lines 25-43, col.8) with lipid solutions or aqueous lipid emulsions, with physiological saline and about 50% fatty acid. Polyethylene glycol, may also be used (Col.10, lines 38-39) as can soybean oil (Col.8, top). Various forms including lyophilized (Col.11, top) for parental infusion, are taught, as are the generic soybean lipid emulsion (Col. 30, lines 45-56) characterized instantly as INTRA lipid, or castor oil (Col.32, lines 15-20). Glycerol is used in the composition as at Col. 35, lines 8-16; Example 10-5.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-~~68~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al 5,430,057 in view of Sugiyama et al 5,651,991.

Anderson discloses the instant invention composition suitable for the application, at the instant concentrations except for use of all forms instead of limited examples, as solvent components.

Sugiyama however, teaches the instant elements, equivalent to the carriers of Anderson but in forms for lipid drugs, in a similar format of both the instantly claimed invention and

Art Unit: 1616

Anderson. Sugiyama teaches one having ordinary skill in the art would be motivated to perform this modification in order to prevent up take by R.E. System (Col.7, top).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize drug vehicle compositions as taught by Anderson to provide any of the Anderson forms, modified to increase applicability dependent upon the drug of interest.

The particular mix of actives is a function of the compatibility of these components with each other, and with the desired drug of choice.

The selection of each component is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.

There is no unusual and/or unexpected results obtained since the prior art is well aware of the use of compounds for enhancement and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater of different level of prior art expectation as claimed. All these components are old, art recognized forms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday-Friday from 7 am to 5:30 pm.

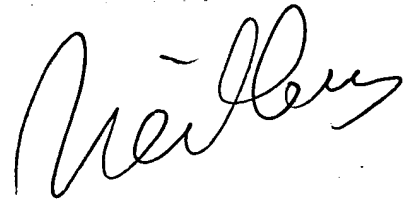
Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy:mv

March 8, 2001

A handwritten signature in black ink, appearing to read "Neil S. Levy". The signature is fluid and cursive, with a large initial "N" and "L".

NEIL S. LEVY  
PRIMARY EXAMINER